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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,211	02/13/2004	Markku Anttila	2630-127	2487

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EXAMINER
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GEMBEH, SHIRLEY V

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/777,211

Applicant(s)

ANTTILA, MARKKU

Examiner

Shirley V. Gembeh

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The response filed **August 08, 2006** presents remarks and arguments to the office action mailed **May 04, 2006**. Applicants' request for reconsideration of the rejection of claims in the last office action has been considered.

Applicants' arguments, filed August 08, 2006, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

#### **Status of claims:**

Claims 1-9 are pending.

Claims 1, 6 and 9 are amended.

#### ***Maintained Claim Rejections - 35 USC § 112***

Claims 7-9 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating osteoporosis, does not reasonably provide enablement for preventing osteoporosis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

Applicant argues that the art of record teaches prevention of osteoporosis and prevention is a legitimate clinical target, and raloxefene (another SERM) is APPROVED BY FDA (see remarks page 5+).

In response, Examiner, will like to emphasis while the approval of the use of the term preventing is okay with the FDA, Applicant should also bear in mind that this is not the FDA, the rules and regulation are not the same.

Secondly, Applicant in the specification has not shown by or with data how this prevention takes place, at what stage does one start preventing. Please note that prevention is interpreted as to never occur.

Applicant has not shown how any of the claimed diseases can be prevented. The two examples given in the specification are directed to showing the drug effect with meal in the serum and nothing to the effect of treating let alone preventing.m

Also, pages 5- 6 of the remarks (last two lines on page 5 cont. on page 6), is clearly why the term prevention is not allowed. Nowhere in the specification did Applicant define the term prevention as to be interpreted, thus allowing the examiner to use the broadest term reasonable.

Applicant's arguments filed have been fully considered but they are not persuasive. The rejection of the above claims are maintained.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biskobing Expert Opinion Invest. Drug taken with of WO 97/32574 in view of Halonen et al. US 6,245,819).

Applicant argues that food was not specifically described in the claimed patent.

1. In response, Applicant has not defined what food is, thus the rejection is rightfully maintained. Material, usually of plant or animal origin, that contains or consists of essential body nutrients, such as carbohydrates, fats, proteins, vitamins, or minerals, and is ingested and assimilated by an organism to produce energy, stimulate growth, and maintain life.
2. A specified kind of nourishment: *breakfast food; plant food*.
3. Nourishment eaten in solid form: *food and drink*.
4. Something that nourishes or sustains in a way suggestive of physical nourishment: *food for thought; food for the soul. Thus water falls in this category, therefore is a food*.

Please note that supplements are also termed as food.

Rejection has been fully considered but found unpersuasive, even though it is not clearly recited, in the patent, it did not exclude administration of the drug before, during or after. Most drugs are taken with food in order to prevent patient from

feeling nausea, vomiting or any other symptom related with taken drugs on an empty stomach. As cited by familydoc.org, not all medicines are affected by food intake the general concept of why food can be taken before, after or during is discussed (see enclosed reference).

Careful thought has been given to the remarks, but are found unpersuasive and the rejection is maintained as in the office action on record.

***Maintained Double Patenting***

I. Claims 1-9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent Application No. 10783092 Although the conflicting claims are not identical, they are not patentably distinct from each other.

II. Claims 1-9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent Application No. 11183185 Although the conflicting claims are not identical, they are not patentably distinct from each other.

III. Claims 1-9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent Application No. 11201098. Although the conflicting claims are not identical, they are not patentably distinct from each other.

IV. Claims 1-9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6984665. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Applicant argues that none of the applications or the patents applied in the rejection contain disclosure of enhancing bioavailability.

In response, this finding is unpersuasive, because this is an obviousness double patenting, does not need to have every single disclosure. The scope as a whole is the same. Administering the drug with or without food is not going to change the mechanism of action of the drug in the system, once the drug gets in the system it is available.

Careful thought has been given to the remarks, but are found unpersuasive and the rejection is maintained as in the office action on record.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVG  
10/26/06

*Ardin H. Marschel 10/30/06*  
ARDIN H. MARSCHEL  
SUPERVISORY PATENT EXAMINER